

COHN LIFLAND PEARLMAN
HERRMANN & KNOPF LLP
Peter S. Pearlman
Park 80 Plaza West-One
Saddle Brook, NJ 07663
201-845-9600
Attorney for Plaintiffs

[Additional Counsel listed on signature page]

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

<p>LOUISIANA WHOLESALE DRUG CO., INC., BURLINGTON DRUG CO. INC., and MIAMI-LUKEN, INC. on behalf of themselves and all others similarly situated,</p> <p style="text-align: center;">Plaintiffs</p> <p>v.</p> <p>MERCK & CO., INC. and MERCK SHARP & DOHME PHARMACEUTICALS SRL</p> <p style="text-align: center;">Defendants</p>	<p>CIVIL ACTION NO.:</p> <p><u>JURY TRIAL DEMANDED</u></p> <p>CLASS ACTION COMPLAINT</p>
--	---

Plaintiffs, on behalf of themselves and the class defined below, bring this antitrust action against Defendants Merck Sharp & Dohme Pharmaceuticals, SRL and Merck & Co., Inc. (collectively "Merck" or "Defendants") and allege as follows based upon personal knowledge as to matters relating to themselves and upon the investigation of their counsel and information and belief as to all other matters:

NATURE OF THE CASE

1. This case arises from Merck's anticompetitive scheme to block entry of generic competition in order to maintain its monopoly power in the United States over Singulair ® (montelukast sodium) and any actual or potential AB-rated generic competitors. Merck's scheme was intended to, and succeeded in, allowing it to charge supracompetitive prices for

scheme was intended to, and succeeded in, allowing it to charge supracompetitive prices for montelukast sodium, causing Plaintiffs and members of the class to pay overcharges on their purchases.

2. Merck sells montelukast sodium in the United States and its territories under the brand name Singulair. Singulair was approved by the United States Food & Drug Administration ("FDA") in February 1998 for the treatment of asthma and seasonal allergies.

3. As alleged in greater detail herein, Merck engaged in a scheme involving U.S. Patent No. 5,565,473 (the "'473 patent") issued by the United States Patent and Trademark Office ("PTO"). This misconduct involved, *inter alia*, fraudulently inducing the PTO to issue the '473 patent, the improper listing of the '473 patent with the FDA, and improperly asserting infringement claims based on the '473 patent.

4. Merck acquired the '473 patent through a pattern of material misrepresentations to the PTO. As set forth in more detail below, Merck deliberately concealed its own prior art from the PTO, and misled the patent examiner in other material ways. Absent this fraudulent and deceptive conduct, the '473 patent would not have issued.

5. Merck proceeded improperly to list the '473 patent with the FDA, in order to position itself to enforce the patent by filing patent infringement claims against any potential competitor seeking FDA approval to manufacture and sell a competing, generic version of Singulair. Merck knew that the mere filing of such patent infringement claims would block the market entry of potential competitors, irrespective of the merits of the claims.

6. Merck then instituted a baseless lawsuit against a potential competitor for the purpose of forestalling generic competition. In early 2007, Teva Pharmaceuticals Industries, LTd. ("Teva"), filed an application with the FDA for approval to market a generic version of Singulair. In May 2007, Merck filed a patent infringement lawsuit against Teva, even though Merck knew that the '473 patent was improperly procured and that no reasonable claim of infringement could be based upon it.

7. Merck filed this lawsuit not for any legitimate purpose, but because it knew that the mere filing of such litigation would raise barriers to the entry of generic competition, including automatically delaying the FDA's granting of final marketing approval to Teva's generic version of Singulair. Without such approval, generic manufacturers cannot bring their products to market.

8. Subsequent to Teva's application for approval to market a generic form of Singulair, other potential competitors filed similar applications with similar allegations.

9. By its unlawful acts, Merck has willfully and unlawfully maintained its monopoly power over Singulair and generic and bioequivalent forms of the drug to this day.

10. Through its illegal conduct, Merck has unlawfully deprived Plaintiffs (and other direct purchasers who comprise the class defined below) of access to substantially lower-priced generic versions of Singulair. Merck has thus caused Plaintiffs and the class to overpay for montelukast sodium by many millions of dollars.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. §§ 1331 and 1337.

12. Venue is proper in this District under 28 U.S.C. § 1391 and 15 U.S.C. §§ 15(a) and/or 15 U.S.C. § 22 because Defendants transact business, committed an illegal or tortious act, have an agent, and/or are found within this District, and/or because a substantial portion of the events described below have been carried out in this District.

PARTIES

13. Plaintiff Louisiana Wholesale Drug Co., Inc. ("LWD") is a privately held pharmaceutical wholesaler with its principal place of business at 2085 I-49 S. Service Rd., Sunset, Louisiana 70584. During the Class Period, as defined below, LWD purchased Singulair directly from one or more Defendants at supra-competitive prices and was injured by the illegal conduct described herein.

14. Plaintiff Burlington Drug Company, Inc. ("Burlington") is a privately held company with its principal place of business at 91 Catamount Drive, Milton, Vermont. During the Class Period alleged herein, Burlington purchased Singulair directly from one or more Defendants at supra-competitive prices and was injured by the illegal conduct described herein.

15. Plaintiff Miami-Luken, Inc. ("Miami-Luken"), an Ohio corporation, is a full line pharmaceutical wholesaler with its principal place of business at 265 Pioneer Blvd., Springboro, OH 45066. During the Class Period alleged herein, Miami-Luken purchased Singulair directly from one or more Defendants at supra-competitive prices and was injured by the illegal conduct described herein.

16. Defendant Merck & Co., Inc. is a New Jersey corporation with its headquarters located at Whitehouse Station, New Jersey. Merck is a global company that researches, develops, and markets pharmaceutical drug products. Merck sells its pharmaceutical drug products primarily to drug wholesalers and retailers, hospitals, government agencies, and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions.

17. Defendant Merck Sharp Dohme Pharmaceuticals SRL is a corporation organized and existing under the laws of Barbados that maintains its principal place of business at Chancery House, High Street, Bridgetown, Barbados. MSD is a subsidiary of Merck & Co. Inc., and Merck & Co. Inc. purchases montelukast sodium used in Singulair from MSD pursuant to a supply distributorship agreement.

INTERSTATE COMMERCE

18. During all or part of the class period (defined below), Defendants manufactured and sold substantial amounts of Singulair in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States and its territories.

19. At all material times, Singulair manufactured and sold by Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

20. During all or part of the class period, Defendants transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Singulair.

21. In furtherance of its efforts willfully to obtain and/or maintain monopoly power over Singulair and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

22. Defendants' efforts willfully to obtain and/or maintain monopoly power over Singulair and its generic equivalents, as alleged herein, have substantially affected interstate and foreign commerce.

CLASS ALLEGATIONS

23. Plaintiffs bring this action under Rule 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and the following class (the "Class"):

All persons and entities in the United States and its territories who purchased Singulair directly from Defendant Merck & Co., Inc. at any time from August 20, 2003, until the effects of Defendant's anticompetitive conduct cease (the "Class Period"). Excluded from the Class are Defendants and their parents, employees, subsidiaries, and affiliates, and all government entities.

24. The Class is so numerous that joinder of all members is impracticable. Plaintiffs believe that the Class numbers one hundred or more.

25. There are questions of law or fact common to the Class, including:

- a. whether Merck willfully obtained and/or maintained monopoly power over montelukast sodium and its actual or potential generic equivalents;
- b. whether the '473 patent was obtained through fraud and/or inequitable conduct;
- c. whether Merck's lawsuit asserting infringement of the '473 patent was

- d. baseless;
whether Merck filed such lawsuit for the purpose of preventing or delaying competition; and
- e. whether, and to what extent, Merck's conduct caused direct purchasers of Singulair to be overcharged and therefore injured.

26. These and other questions of law and fact are common to the members of the Class and predominate over any questions affecting only individual members.

27. Plaintiffs' claims are typical of the claims of the Class because all Class members suffered antitrust injury in the same way as a result of Defendants' wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

28. Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel experienced in class action and pharmaceutical antitrust litigation, and Plaintiffs have no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

29. A class action is superior to any other available methods for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

BACKGROUND

Federal Regulation of Prescription Drugs

A. Brand-Name Drugs vs. Generic Drugs

30. The brand-name prescription drugs industry is one of the most profitable industries in the United States. Over \$250 billion was spent on prescription drugs in the United States in 2005, with \$229.5 billion spent on brand-name drugs. The cost of prescription drugs

has been rising at a rate of 14% to 18% per year. From 2004 to 2007, brand name drug prices increased by an average of 21%, while generic drug prices decreased by an average of 12.8% during the same period.

31. Securing the availability of generic drugs is one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which must be approved by the FDA, by law have the same active chemical composition and provide the same therapeutic effects as the brand-name drugs to which they correspond.

32. The FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs. To be deemed a therapeutic equivalent, and receive an "AB" rating from the FDA, the generic drug must contain the same active ingredient(s), dosage form, route of administration, and strength. According to the FDA, a bioequivalent drug rated "AB" may be substituted for the reference pioneer or branded drug.

33. Once the safety and effectiveness of a new prescription drug is approved by the FDA, the drug may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be purchased from a licensed pharmacist. The pharmacist, in turn, must fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug approved by the FDA is available.

34. If a generic version of a brand-name drug exists and the physician has not specifically indicated to the pharmacist to dispense the branded drug then: (i) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug, and (ii) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the option of purchasing the branded drug or the AB-rated generic drug at a lower

price.

35. Once a physician writes a prescription for a brand-name drug such as Singulair, that prescription defines and limits the market to the drug name or its AB-rated generic equivalents. Only drugs that are AB-rated by the FDA may be substituted by a pharmacist for a physician's prescription for the brand-name drug.

36. Generic drugs are priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office ("CBO") concluded that generic drugs save purchasers between \$8 billion and \$10 billion a year. A study released earlier this year by the Generic Pharmaceutical Association based on an independent analysis of data from IMS showed that the use of generic drugs has saved consumers, patients, and healthcare providers \$734 billion over the past ten years (1998-2008), with approximately \$121 billion in savings in 2008 alone.

37. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand-name drug during periods of generic marketing exclusivity. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.

38. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition. The 1998 CBO study estimated that, at that time, generic drugs captured at least 44% of the brand-name drug's market share in just the first year of sale.

B. Federal Scheme for Approval of Pioneer Drugs

39. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301, *et seq.* (The "FFDCA") regulates the manufacture and distribution of drugs and medical devices in the United States. Under the FFDCA, approval by the FDA (the governmental body charged with the regulation of the pharmaceutical industry) is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. §335(a). Premarket approval for a

new drug must be sought by filing a new drug application (“NDA”) with the FDA under §335(b) of the FFDCA, demonstrating that the drug is safe and effective for its intended use.

40. New drugs that are approved for sale in the United States by the FDA are often covered by patents, which provide the patent owner with the ability to seek to exclude others from making, using, and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patent, plus any extension of exclusivity granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §355 (“Hatch-Waxman Act”).

41. Pursuant to 21 U.S.C. § 335(b), in its NDA, the pioneer drug manufacturer must list those patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. If a particular patent does not meet this test with respect to the NDA, the patent cannot properly be listed with the FDA. Once the NDA is approved by the FDA, any such patents are listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

42. Federal regulations impose strict limitations on the types of the patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. §314.53. One such limitation is imposed by 21 C.F.R. §314.53(b), which explicitly prohibits NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

43. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has regrettably become common for brand-name pharmaceutical companies to list in the Orange Book any and every patent they can obtain, in order to force generic manufactures to file what, as described below, is commonly known as a Paragraph IV Certification.

44. The FDA does not police the listing of patents. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing in the Orange Book. The FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) (“FDA does not have the expertise to review patent information . . .”).

45. The FDA’s role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing. For that reason, courts have held that the patent listing process is not “government petitioning”, and Defendants are specifically not entitled to rely upon any defense of immunity pursuant to the *Noerr-Pennington* doctrine.

C. Approval of Generic Drugs

46. Congress enacted the Hatch-Waxman Act in 1984. The Hatch-Waxman Act was principally designed to streamline the process by which generic drugs are brought to market. The Hatch-Waxman Act simplified the regulatory hurdles faced by prospective generic drug manufacturers by eliminating the need for such manufacturers to file lengthy and costly NDAs. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand-name drug with an approved NDA by filing an Abbreviated New Drug Application (“ANDA”), pursuant to 21 U.S.C. §355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand-name drug.

47. Under the Hatch-Waxman Act, a generic drug manufacturer’s ANDA must contain a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii) addressing the patents, if any, listed in the Orange Book as applying to the brand-name or pioneer drug. Four types of certifications are available:

- I. The brand name manufacturer has not filed patent information with the FDA (a “Paragraph I Certification”);
- II. The patent or patents listed in the Orange Book have expired (a

“Paragraph II Certification”);

- III. The patent or patents listed in the Orange Book will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a “Paragraph III Certification”); or
- IV. The patent or patents listed in the Orange Book are invalid or not infringed by the generic manufacturer’s product (a “Paragraph IV Certification”).

21 U.S.C. §355(j)(2)(A)(vii).

48. If a generic manufacturer files a Paragraph IV Certification, seeking to market the generic drug before patent expiration and asserting that any listed patent is invalid or will not be infringed, the brand-name manufacturer has the opportunity to delay the generic manufacturer’s receipt of final FDA approval, and, thus, its ability to come to market. This is because a generic manufacturer filing a Paragraph IV Certification must promptly give notice of this fact to both the NDA owner and the owner of the patent(s) at issue, and this certification may constitute a “technical act of infringement” under the Hatch-Waxman Act.

49. The filing of a Paragraph IV Certification thus creates jurisdiction in the federal courts to entertain a patent infringement action, and gives the NDA holder forty-five days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. §271(e)(2). *See* 21 U.S.C. §355(j)(5)(B)(iii). If such a suit is initiated, the FDA’s approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. §355(j)(5)(B)(iii).

50. Because of this thirty-month stay of ANDA approval, the mere filing of an infringement action in response to a Paragraph IV Certification, regardless of the action’s underlying merit, gives the brand-name company the equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without requiring the brand

company to establish likelihood of success on the merits, irreparable harm, that the balance of hardships tips in its favor, or that the public good is served by the blocking of entry.

51. As a practical matter the brand name company obtains an injunction simply by filing a complaint, even a complaint with little or no merit, as it automatically protects its monopoly for up to two-and-a-half years while the infringement action winds its way through the court system. Moreover, the brand name company has an incentive to stall the progress of the litigation. There are no disgorgement provisions for profits earned during the thirty-month period of exclusivity if a court eventually determines that the suit was without merit.

52. An improper Orange Book listing also has additional anticompetitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of marketing exclusivity in relation to other generic manufacturers. 21 U.S.C. §355(j)(5)(B)(iv). Absent an improper Orange Book listing, no Paragraph IV Certification would be required and, thus, no generic company would receive any 180-day exclusivity; rather, multiple generic competitors would enter the market simultaneously, resulting in prices even lower than one would find during the 180-day exclusivity period when only one generic manufacturer is permitted to market its product.

53. Defendants were at all times fully familiar with the ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Amendments.

MERCK'S ANTICOMPETITIVE CONDUCT

A. Merck's Inequitable Conduct and Fraud on the PTO to Obtain the '473 patent

54. The '473 patent issued from the following series of patent applications: U.S. Appl. Ser. No. 08/392,592 ("the '592 Application"), which is a continuation of U.S. Appl. Ser.

No. 07/774,414 (“the ‘414 Application”), now abandoned, filed Oct. 10, 1991, which is a continuation-in-part of U.S. Appl. Ser. No. 741,888 (“the ‘888 Application”), filed Aug. 8, 1991, now abandoned, which is a continuation-in-part of U.S. Appl. Ser. No. 596,887 (“the ‘887 Application”) filed Oct. 12, 1990, now abandoned. A continuation-in-part application incorporates new matter into an application while a continuation application does not. Each application, as required by law, contains an oath by each of the named inventors in which each declares under penalty of fine and/or imprisonment, that he is an original, first and joint inventor of the subject matter claimed in the application and that the statements made in the oath are true. Each inventor also acknowledges his obligation to disclose information material to the application to the Patent Office. A separate oath was signed for each of the applications identified above.

55. During its efforts to procure the ‘473 patent from the PTO, Merck deliberately engaged in inequitable and fraudulent conduct in its statements and submissions to the PTO. Merck’s inequitable and fraudulent misrepresentations and omissions were intended to deceive and did in fact deceive the PTO, and resulted in the issuance by the PTO, on October 15, 1996, of the ‘473 patent.

56. At the time when the ‘887, ‘888, ‘414 and ‘592 Applications were filed, PTO Rule 56 required an applicant (including inventors, attorneys, agents and others involved in the prosecution of a patent application) to disclose to the PTO information they are aware of “which is material to the examination of the application.” Such information includes any prior art which may form the basis for a rejection under 35 U.S.C. §102 (novelty) or 35 U.S.C. §103 (obviousness). PTO Rule 56 further requires, when an applicant files an application that relates to an earlier filed application, that the applicant disclose any information relevant to the subject

matter of the claim of which the applicant learned between the time of filing of the original application and the time of the subsequent application.

57. Under §103, an invention cannot be patented if it would have been obvious to “a person having ordinary skill in the art” in light of the “prior art.” Prior art is a term of art that includes, among other things, material patented or described in a printed publication anywhere in the world prior to the invention by the applicant.

58. Two highly material articles written by Dr. Robert Young, a member of the research team at Merck Frosst Center for Therapeutic Research (“MF-CTR”), published prior to the filing of the ‘887 Application, were deliberately concealed by Merck rather than being disclosed to the PTO in the ‘887, ‘888, ‘414 or ‘592 Applications. These articles were: Robert N. Young, “Structural Analysis of Sulfido-Peptide Leukotrienes: Application to the Design of Potent and Specific Antagonists of Leukotriene D₄,” *Advances in Prostaglandin, Thromboxane, and Leukotriene Research*, 1989, vol. 19, pages 643-646 (“Young 1989”), published well over 1 year prior to the filing of the ‘887 application; and Robert N. Young, “The Development of New Anti-Leukotriene Drugs: L-648,051 and L-649,923, Specific Leukotriene D₄ Antagonists,” *Drugs of the Future*, 1988, vol. 13, pages 745-759, (“Young 1988”), published in 1988, almost two years prior to the ‘887 application.

59. The author of these withheld references, Dr. Young, was an MF-CTR researcher. The articles were reviewed and approved for publication by Gabriel Lopez, the same Merck & Co. Inc. attorney who drafted the ‘473 patent applications and who handled most of the prosecution of the applications.

60. Dr. Young also presented the same material to his fellow MF-CTR researchers, including inventors named in the ‘473 patent, prior to their alleged invention. A primary

inventor named in the '473 patent has conceded in deposition testimony that key insights behind the purported invention in the '473 patent first occurred to Merck scientists either during that presentation or shortly thereafter, and were prompted directly by the presentation made by Dr. Young. Those insights occurred to the inventors then for the simple reason that they were obvious from the prior art of Dr. Young that was presented at that time. Upon information and belief, the inventors have conceded, in depositions in pending patent infringement litigation, that they believe the Young references are highly relevant to the '473 patent. Nevertheless, Merck intentionally concealed from the PTO both of Dr. Young's prior art references from which key concepts behind the purported invention of the '473 patent directly originated.

61. Both articles by Dr. Young suggest substitution of a secondary or tertiary alcohol group for the primary alcohol – a central issue during prosecution of the '473 patent.

62. A third, also highly material reference was edited by another MF-CTR researcher, Dr. Joshua Rokach, and includes chapters written by other MF-CTR researchers. Joshua Rokach, Ed., *Leukotrienes and Lipxygenases: Chemical, Biological and Clinical Aspects, Bioactive Molecules volume II*, pages 490-491, Elsevier, was published in 1989 ("Rokach 1989"). Although published within one year of the '887 application, it is prior art to the new material, including the montelukast compound, disclosed in the '888 and '414 continuation-in-part applications.

63. While the Rokach reference is mentioned in the patent specification, a copy was not provided to the Examiner even though a request was made for copies of all the references discussed in pages 1-3 of the Specification. *See* Office Action dated March 18, 1991.

64. In statements made by Merck during its prosecution of the '473 patent about the Rokach reference, Merck deliberately presented a misleading description of a text solely relating

to leukotrienes, and failed to identify the extensive work in the Rokach reference on the development and design of leukotriene antagonists.

65. These three pieces of prior art, with which both the inventors and Merck itself were intimately familiar, are all critical to the montelukast invention, since montelukast can be constructed using the steps laid out in the Young publications using the starting compound described in Rokach.

66. Merck's intent to mislead and defraud the PTO, in choosing not to cite its own prior art publications from which key concepts behind the '473 patent had been directly derived by the Merck inventors, is clear from the prosecution of the four applications leading to the issuance of the '473 patent.

- (a) In the first PTO Office Action, the examiner cited four new references (Huang, Mohrs, Young and Mohrs II) and two foreign references identified in the '887 Application, stating that it would have been obvious to combine the heterotetrahydrocarbazole moieties taught in the acknowledged prior art as leukotriene inhibitors with the quinolin moieties taught in Huang, Mohrs, Young and Mohrs II.
- (b) In its response to the Office Action (dated June 18, 1991), Merck misleadingly asserted that "Young, *et al.*'s compounds differ significantly from the present invention in that the Q side chains is attached directly to the benzene ring by a heteroatom; whereas the present compounds have the Q side chains insulated from the benzene ring by a saturated carbon atom. Furthermore, the compounds of Young, et al. have one polar Q per side-chain, whereas the present compounds have two such groups." Merck went on further to assert that "the present compounds differ from EP 318,093 in that Q 2 is a secondary or tertiary alcohol or amine." Merck made these deceptive and misleading statements despite

knowing that Merck's own prior art in the Young 88, Young 89 and Rokach references had fully revealed and disclosed the same concepts that Merck claimed distinguished the '473 patent from other prior art.

- (c) The examiner made a similar rejection in the first Office Action in the '888 application and rather than respond, Merck abandoned the application.
- (d) At no time during the prosecution of the '887, '888, '414 or '592 applications did Merck disclose the Young 1988 or the Young 1989 publications or accurately describe the teachings of the Rokach publication – all of which contain teachings that illustrate the distinctions heavily emphasized by Merck in the statements that it made to the PTO to overcome the PTO's initial rejection of the claims in the '473 Patent.

67. In stating to the PTO that the prior art cited by the examiner does not disclose the claimed combination of elements, even while being aware that the very same combination of elements was fully disclosed in Merck's own, much more relevant prior art (which Merck concealed), Merck intended to and did mislead and deceive the PTO and obtain the '473 patent by fraud. Merck's intent to mislead and defraud the PTO is further evidenced by Merck's failure to disclose an April 1988 Abstract written by a group of Merck employees including Michel Belley and Serge Leger, two of the named inventors of the '473 patent. According to Dr. Rokach, a Merck employee at the time and another co-author of the abstract, the abstract disclosed the development and structure of the L-660,711 and described it as "extremely potent *in vitro* ($PA_2 = 9.4$) and binds to the LTD_4 receptor with almost equal affinity to its natural ligand. L-660,711 is also very potent *in vivo*, against LTD_4 and antigen challenge showing excellent bioavailability and duration of action." The Abstract is identified as Zamboni, R.; Belley, M.; Champion, E.; Charette, L.; DeHaven, R.; Frenette, R.; Ford-Hutchinson, A.W.; Gauthier, J.Y.; Jones, T.R.; Leger, S.; MacFarlane, C.S>; Masson, P.; Piechuta, H.; Pong, S.S>; Rokach, J.; Williams, H.; and Young, R.N.; Taipei Conference on Prostaglandin and Leukotriene Research, Taipei, Taiwan, April 22-24, 1988, Abstract Book p. 37 (the "Taipei Abstract") and

cited as the source of this information in Rokach '89.

68. As named inventors of the '473 patent, Belley and Leger each signed an inventor's oath in which each acknowledged his sworn obligation to disclose information "which is material to the examination of the application." In direct violation of those oaths, neither the Taipei Abstract nor Dr. Rokach's disclosure of the contents of the Abstract was disclosed to the PTO.

69. Even though Young made substantial contributions to the invention claimed in the '473 patent, Merck twice omitted to name Young as an inventor of the patent, first when initially applying for the patent, and then a second time when Merck petitioned to correct the inventorship specified in the patent. Had Young been named in the patent applications as one of the inventors, it would have enhanced the possibility that the PTO might independently have discovered Young's prior art. On information and belief, Merck omitted Young's name from the listed inventors in order to facilitate its effort, as described above, to conceal Young's prior art from the PTO and to obtain the '473 patent by fraud.

70. The PTO examiner would not have allowed the claims of the '473 patent if Merck's own prior art had been disclosed to him by Merck in its applications for the patent, or if Merck had not made its intentionally deceptive and misleading assertions to the PTO about other prior art that had been uncovered by the examiner. Upon information and belief, the inventors of the '473 patent have specifically admitted in deposition testimony that the Young 1989 publication would have been important and material to the examiner in deciding whether to grant the '473 patent. In addition, the PTO examiner's initial rejection of the patent application was overcome only by arguments made by Merck, seeking to distinguish other prior art, that were not true as to Merck's own prior art that had been deliberately concealed from the PTO.

71. A Request for Reexamination of the '473 patent has been granted by the U. S. Patent and Trademark Office. However, issues of fraud, inequitable conduct and violations of the duty of disclosure to the PTO will not be presented or discussed in that reexamination, because the Manual of Patent Examination Procedure Sections 2014 and 2258 clearly state that

such issues are outside the scope of a reexamination proceeding under 35 USC 302-307 and 37 CFR §1.552. MPEP 2217 also states that such issues “will not be considered when making the determination of the request [for reexamination] and should not be presented in the request.”

72. Merck not only procured the ‘473 patent by inequitable conduct and fraud, it then listed that fraudulently-obtained patent in the FDA’s Orange Book with the knowledge that the ‘473 patent was invalid and unenforceable by virtue of that fraud, and with the intent and effect of enforcing its fraudulently-obtained patent and thereby preventing competition in the relevant market. The FDA’s role in the patent listing process is purely ministerial and does not constitute “government petitioning” that could give rise to a defense of immunity pursuant to the *Noerr-Pennington* doctrine.

73. But for Merck’s fraud on the PTO, the ‘473 patent would not have issued. With no ‘473 patent issuing, Merck was entitled to only five years of marketing exclusivity from the date of FDA approval of Singulair on February 20, 1998. As a “New Chemical Entity,” Merck received five years marketing exclusivity, or “NCE” exclusivity, that expired on February 20, 2003. 21 USC §355(a)(3)(E)(ii) and 355(j)(5)(F)(ii). As no patent would have issued, no such patent could be wrongfully listed with the FDA. With no patent listed with the FDA for Singulair, generic competitors would have been eligible to file Paragraph I certifications (no applicable patent) with their ANDAs seeking approval for a generic Singulair. With only NCE exclusivity in effect, Teva and other generic applicants could have filed ANDAs with Paragraph I certifications as soon as February 20, 2003. FDA ordinarily approves or disapproves an application within no more than 180 days of its acceptance, as is reflected in the governing statutory language. 21 USC §355(j)(5)(A). Per FDA internal policies and procedures, these Paragraph I certifications are given the highest priority. FDA MAPP 5240.3. Thus, FDA would have given these applications their highest priority, and would have approved the applications in a much shorter review time than in reality, and as early as mid-August, 2003. But for Merck’s misconduct, one or more competitors would have already begun marketing AB-rated generic versions of Singulair.

74. In the alternative, but for the fraudulent conduct described above, Teva would have filed its ANDA containing a Paragraph I certification in February 2007, just as it filed ANDAs with Paragraph IV certifications in reality. Under the statutory scheme described in the preceding paragraph, these applications would have been approved by August 2007, six months after application was made. Thus, generic competition to Singulair would have existed as soon as August 2007. 74. Further in the alternative, but for the fraudulent conduct described above, Teva would have filed its ANDA containing a Paragraph I certification in February 2007, just as they filed ANDAs with Paragraph IV certifications in reality. With no litigation and accompanying 30-month stay, these applications would have received final approval on the date upon which they have now actually received tentative approval. Thus, generic competition to Singulair would have existed as early as May 2009.

75. Under any of these alternative scenarios, direct purchasers have been overcharged for their purchases, and have suffered antitrust injury as a result of Merck's conduct.

B. Merck's Improper Listing of the '473 patent in the Orange Book

76. As described above, Merck obtained the '473 patent by willful fraud on the PTO.

77. As the '473 patent was fraudulently obtained, it is unenforceable.

78. As a wrongfully obtained and unenforceable patent, the '473 patent was not eligible for listing in the FDA Orange Book at the time Merck so listed it.

79. As Merck knowingly listed an ineligible patent in the Orange Book, Merck has deliberately and knowingly misused the FDA's Orange Book listing process in an effort to exclude competition for Singulair.

80. But for Merck's unlawful listing of the '473 patent in the Orange Book, Teva would have filed a Paragraph I certification with its ANDA for montelukast sodium, alleging that no patents were listed for that product. Under the terms of the statute, a Paragraph I certification is not an act of infringement, and Merck has no basis upon which to sue.

81. Thus, but for Merck's unlawful listing of the '473 patent, generic competition for Singulair should again have entered pursuant to one of three alternative scenarios explicated in

Paragraphs 69-71 or otherwise.

C. Merck's Filing of a Sham Lawsuit

82. In December 2006, Teva filed ANDA No. 78-605 for 10-mg montelukast sodium. Teva's ANDA contained a Paragraph IV certification to the '473 patent, asserting that the 473 patent is invalid, unenforceable, and/or non-infringed. As the first generic company to file a Paragraph IV certification to this patent, Teva is entitled to the accompanying 180 days of marketing exclusivity provided for in the Hatch-Waxman Act.

83. In early 2007, Teva filed ANDA No. 78-723 with the FDA, seeking approval to market generic montelukast sodium tablets in 4-mg and 5-mg dosages. Teva's ANDA for these dosages also contained a Paragraph IV certification, asserting that the '473 patent is invalid, unenforceable, and/or non-infringed. As the first generic company to file a Paragraph IV certification to this patent, Teva is entitled to the accompanying 180 days of marketing exclusivity provided for in the Hatch-Waxman Act.

84. In accordance with 21 U.S.C. §355(j)(5)(B), Teva sent Merck a Paragraph IV certification notification letter in April 2007.

85. On May 14, 2007, Merck filed suit against Teva, alleging that the Paragraph IV certification was an act of infringement, thereby invoking the Hatch-Waxman Act's automatic 30-month stay. This stay remains in effect as of the date of this filing and will expire on or around November 2009.

86. Merck filed the complaint claiming infringement of the '473 patent by Teva with actual knowledge that the '473 patent had been procured by fraud on the PTO and was invalid and unenforceable, and with the anti-competitive purpose of delaying competition in the market for Singulair and its generic equivalent.

87. At the time when Merck filed the patent infringement complaint against Teva, Merck knew or should have known that the '473 patent was invalid under one or more provisions of Title 35, United States Code, including 35 U.S.C. §103(a).

88. At the time when Merck filed its patent infringement complaint against Teva, Merck knew or should have known that the '473 patent was unenforceable because of inequitable conduct before the PTO during prosecution of the applications leading to the '473 patent.

89. At the time when Merck filed its patent infringement complaint against Teva, Merck lacked a good faith basis for believing that Teva had infringed any valid claim of the original '473 patent.

90. Merck brought its infringement action against Teva for the improper purpose of delaying FDA approval of Teva's ANDA, and thereby preventing Teva from entering the market for montelukast sodium as a generic competitor to Singulair and preventing Teva from providing generic competition for Merck's Singulair.

91. On May 21, 2009, the FDA granted tentative approval to Teva's ANDA 78-605 for 10-mg montelukast sodium tablets, and on June 25, 2009 the FDA granted tentative approval to Teva's ANDA 78-723 for 4-mg and 5-mg montelukast sodium tablets. The FDA stated that it could not grant final marketing approval to those applications because the sham patent infringement litigation remains pending and the 30-month stay under the Hatch-Waxman Act has not yet expired. The FDA stated it was otherwise satisfied that Teva's ANDAs met all of the FDA's requirements for final marketing approval.

92. Merck's conduct with regard to the filing of litigation against Teva had wide-ranging impact on other generic competitors.

93. Roxane Laboratories, Inc. ("Roxane") is a manufacturer of generic pharmaceutical products with its headquarters in Columbus, Ohio. Subsequent to Teva's filing of ANDAs for montelukast sodium with Paragraph IV certifications to the '473 patent, Roxane also filed an ANDA for the 10-mg strength, also containing a Paragraph IV certification. On June 16, 2009, Roxane received tentative approval for its ANDA for 10-mg montelukast sodium. But for Merck's anticompetitive conduct, this approval would have been final approval, permitting Roxane to immediately market a generic form of Singulair. This delay of final

approval has caused Plaintiffs to be further overcharged for purchases of Singulair and its generic equivalents.

94. Mylan Laboratories, Inc. ("Mylan") is a manufacturer of generic pharmaceutical products with its headquarters in Canonsburg, PA. Subsequent to Teva's filing of ANDAs for montelukast sodium with Paragraph IV certifications to the '473 patent, Mylan also filed its ANDA, also containing a Paragraph IV certification to the '473 patent. Mylan received tentative approval to market 10-mg montelukast sodium on May 27, 2009, and received tentative approval to market 4-mg and 5-mg montelukast sodium on June 25, 2009. But for Merck's anticompetitive conduct, Mylan would have received final approval, rather than tentative approval, on those dates, and would have been permitted to begin marketing generic forms of montelukast sodium at that time. This delay of final approval has caused Plaintiffs to be further overcharged for purchases of Singulair and its generic equivalents.

95. Merck's unlawful conduct caused the ANDA approval process to be delayed by the FDA and caused Teva to divert its resources from its ANDA application and to expend substantial resources on litigation. Absent the patent lawsuit, Teva, Roxane, Mylan, and the FDA would have had reason to, and would have, focused and directed more of their limited resources into the ANDA approval process for generic montelukast sodium, and sooner than they actually did. Such focus and resources would have brought earlier FDA approval and marketing of generic montelukast sodium by Teva, Roxane, and Mylan. Upon information and belief, absent a 30-month stay, both Teva and FDA would have been incentivized to fast-track the approval of the ANDA, FDA would have issued a final approval more rapidly than they did in actuality, and as soon as 180 days after filing. The 30-month stay is not scheduled to expire until November 2009.

96. By preventing Teva (the first ANDA filer) from obtaining final FDA approval, Merck has created a bottleneck by which Roxane and Mylan are also excluded from the relevant market. By statute, Roxane and Mylan cannot come to market until 180 days after Teva does so. Thus, the anticompetitive scheme has effectively kept out three potential generic competitors in a

market in which generic entry causes immediate, rapid, and in most cases automatic, generic substitution.

97. As a result of Defendant's filing of sham litigation, Plaintiff and the Class have continued to overpay for their purchases of branded and generic forms of Singulair. But for the filing of sham litigation, there would be no accompanying 30-month stay. Upon information and belief, absent a 30-month stay, both Teva and FDA would have been incentivized to fast-track the approval of the ANDA, and would have issued a final approval after the 180 day review period mandated by statute. Thus, but for the sham litigation, Teva would have received final approval as early as August 2007 (180 days after filing), and in any circumstance, substantially earlier than the actual date of tentative approval that occurred in May 2009. As a result, Plaintiff and the Class continue to be overcharged by paying higher prices than would have prevailed in the absence of Defendant's unlawful conduct.

98. In the alternative, but for the filing of sham litigation, the generic competitors would not have filed Paragraph IV certifications to the '473 patent, and Merck would have no artificial act of infringement upon which to base its otherwise baseless patent litigation to enforce the patent. With no patent litigation, there would be no accompanying 30-month stay. Thus, but for the sham litigation, the approval letters sent by FDA to the generic competitors would have been final approval letters, rather than tentative approval letters, and generic montelukast sodium would have been available for sale in or before May 2009.

D. Overarching scheme to violate the Sherman Act

99. The anticompetitive conduct set forth separately above was also part of an overarching scheme by Merck to unlawfully establish and maintain its monopoly in the market for Singulair (montelukast sodium) and exclude any actual or potential AB-rated generic competitors.

100. Merck's overarching scheme consisted of the following conduct:

- (a) the fraudulent procurement of the '473 patent from the PTO;
- (b) the improper listing of the '473 patent in the FDA's Orange Book;

(c) the filing of infringement litigation to enforce the fraudulently obtained '473 patent.

101. Merck's overarching scheme to monopolize this market has worked. Merck remains, to this day, the only supplier of montelukast sodium in the United States and its territories, and those who purchase from Merck continue to suffer overcharges on these purchases.

102. But for Merck's overarching scheme to monopolize the market, generic entry would have occurred as early as August 2003 and no later than May 2009.

EFFECTS ON COMPETITION

103. Merck's scheme to delay the introduction into the U.S. marketplace of any generic version of Singulair has caused Plaintiffs and the Class to pay more than they otherwise would have paid for montelukast sodium.

104. As noted, generic versions of a brand-name drug are initially priced significantly below the brand-name drug. As a result, upon generic entry, direct purchasers rapidly substitute generic versions of the drug for some or all of their brand purchases. As more generic manufacturers enter the market, prices for generic versions of a drug decrease further because of competition among the generic manufactures. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand-name drug at a reduced price. Consequently, brand-name drug manufactures have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial overcharges from that delay.

ANTITRUST IMPACT UPON PLAINTIFFS AND MEMBERS OF THE CLASS

105. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Singulair from Defendants. As a result of Defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their montelukast sodium purchases. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, direct purchasers, such as Plaintiffs,

would have paid less for montelukast sodium by (a) substituting purchases of less-expensive, generic montelukast sodium for their purchases of more-expensive branded Singulair, (b) receiving discounts and/or lowering prices on their remaining branded Singulair purchases, and (c) purchasing generic motelukast sodium at lower prices sooner.

106. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

MONOPOLY POWER

107. At all times referenced herein, Merck has had monopoly power with respect to its Singulair brand. Merck has had at all times the power to maintain the price of Singulair at supra-competitive levels profitably, without losing substantial sales.

108. Significant, non-transitory price increases by Merck to Singulair have not caused a significant loss of sales to other products.

109. Merck sells Singulair at prices well in excess of marginal costs and enjoys high profit margins.

110. Merck has the power to exclude competition.

111. To the extent that defining a relevant product market is necessary in this case, the relevant product market is montelukast sodium in brand or generic forms.

112. The relevant geographic market is the United States and its territories.

113. During and prior to the proposed Class Period, Defendants held a 100% share in the relevant product market in the United States and its territories.

TOLLING OF THE STATUTE OF LIMITATIONS

114. The statute of limitations does not begin to run until the date when potential plaintiffs discover, or with reasonable diligence should have discovered, both its injury and the cause of its injury. At no time prior to more than four years before filing this Complaint did a reasonable means exist by which Plaintiffs here could have discovered Merck's fraud on the

PTO. Defendants' anticompetitive conduct was undertaken in a manner designed to conceal Defendants' wrongdoing from disclosure. Indeed, Defendants sought to conceal their wrongdoing from the PTO itself. As a result, Plaintiffs had no means of acquiring adequate information to provide sufficient notice of Defendants' intentional misconduct more than four years prior to filing the Complaint.

115. Defendants' unlawful conduct before the PTO was based on fraud, and Defendants have fraudulently concealed the existence of the anticompetitive behavior alleged herein. Defendants' fraudulent actions were self-concealing. Moreover, Defendants affirmatively concealed the existence of their unlawful conduct by, among other things, engaging in the misrepresentations detailed above, and maintaining sham litigation based on a patent that Defendants knew was invalid and unenforceable.

116. As a result of Defendants' concealment, Defendants are estopped from asserting the statute of limitations as a defense to any of Plaintiffs' claims. The statute of limitations in this matter was tolled due to Merck's fraudulent concealment.

CLAIM FOR RELIEF

Violation of Section 2 of the Sherman Antitrust Act

117. Plaintiffs incorporate by reference the preceding allegations.

118. At all times relevant, Merck possessed monopoly power in the market for montelukast sodium in the United States which Merck sold as Singulair.

119. In order to prevent generic competition and unlawfully maintain its monopoly in the market for montelukast sodium Merck engaged in the anticompetitive conduct described above that included:

- (a) the fraudulent procurement of the '473 patent from the PTO;
- (b) the improper listing of the '473 patent in the FDA's Orange Book;
- (c) the filing of infringement litigation to enforce the fraudulently obtained '473 patent; and,
- (d) the pursuit of an overarching anticompetitive scheme that involved the conduct

set forth above that was designed to, and did, delay the introduction of generic formulations of Singulair into the market.

120. Merck's conduct constituted unlawful acts of monopolization as set forth in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1985) and *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries*, 508 U.S. 49 (1993) and otherwise enabled it to unlawfully maintain its monopoly in violation of Section 2 of the Sherman Act.

121. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for their montelukast sodium purchases.

122. Plaintiffs and members of the Class have been injured in their business or property by Merck's antitrust violations. Their injury consists of paying higher prices for their montelukast sodium purchases than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent and flows from that which makes Merck's conduct unlawful, and Plaintiffs are the proper entities to bring a case concerning this conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following:

- A. Judgment in their favor and against Defendants for damages representing the overcharges paid by Plaintiffs and the other members of the Class, trebled;
- B. Pre- and post-judgment interest; and
- C. Costs of suit, including reasonable attorneys' fees.

JURY TRIAL DEMANDED

Pursuant to Fed.R.Civ. P. 38(b), Plaintiffs demand a trial by jury of all of the claims asserted in this Complaint that are so triable.

Dated: August 11, 2009

COHN LIFLAND PEARLMAN
HERRMANN & KNOPF LLP



Peter S. Pearlman
Park 80 Plaza West – One
Saddle Brook, NJ 07663
(212) 845-9600
psp@njlawfirm.com

Bruce E. Gerstein
Joseph Oppen
Garwin Gerstein Fisher LLP
1501 Broadway, Suite 1416
New York, NY 10036
(212) 398-0055

J. Douglas Richards
Andrea Hertzfeld
Cohen Milstein Sellers & Toll PLLC
150 E. 52nd Street
30th Floor
New York, NY 10022
(212) 838-7797

Stuart E. Des Roches
Andrew Kelly
Odom & Des Roches, LLP
650 Poydras Street, Suite 2020
New Orleans, LA 70130
(504) 522-0077

David P. Smith
W. Ross Foote
SmithFoote Law Firm
720 Murray Street
P.O. Box 1632
Alexandria, LA 71309-1632
(318) 445-4480

Daralyn J. Durie
Mark A. Lemley
**DURIE TANGRI PAGE LEMLEY
ROBERTS & KENT LLP**
332 Pine Street, Suite 200
San Francisco, CA 94104
Telephone: (415) 362-666
Facsimile: (415) 236-6300

Patrick E. Cafferty
CAFFERTY FAUCHER LLP
101 North Main Street, Suite 450
Ann Arbor, Michigan 48104
Telephone: (734) 769-2144
Facsimile: (734) 769-1207

Andrew D. Manitsky
GRAVEL AND SHEA
76 St. Paul Street, 7th Floor
P.O. Box 369
Burlington, Vermont 05402-0369
Telephone: (802) 658-0220
Facsimile: (802) 658-1456

H. Joseph Gamache
GAMACHE LAW OFFICE, P.C.
P.O. Box 216
Winooski, Vermont 05404-0216
Telephone: (802) 655-4252